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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,381	09/09/2004	Hiroshi Kanai	71532	6389
23872 7590 10/09/2007 MCGLEW & TUTTLE, PC P.O. BOX 9227 SCARBOROUGH STATION SCARBOROUGH, NY 10510-9227			EXAMINER FERNANDEZ, KATHERINE L	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 10/09/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/507,381

Applicant(s)

KANAI ET AL.

Examiner

Katherine L. Fernandez

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-10,12,13 and 16-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-10,12,13 and 16-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Response to Arguments

Applicant's arguments filed July 6, 2007 have been fully considered but they are not persuasive.

After further consideration of the applicant's arguments on claims 1-19, examiner respectfully disagrees.

The combined references of Burke et al. and Papadofrangakis et al. meet the limitations of the amended claims. Specifically, the combined references meet the limitation of plurality of ultrasonic pulses being transmitted at a repeated transmission frequency of a few kHz (see Papadofrangakis, column 6, lines 8-10, referring to the instrument having pulse repletion frequency settings of 4kHz, 8kHz, and 16kHz).

In response to applicant's arguments against the references individually (for example, applicants argument that Papdofrangakis et al. fail to provide any teaching of using the disclosed frequencies to measure ultrasonic backscatter in a wall), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 10 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke (U.S. Patent No. 4,803,994) in view of Papadofrangakis et al. (U.S. Patent No. 4,217,909), and further in view of Kanai et al. ("Noninvasive Evaluation of Local Myocardial Thickening and Its Color-coded Imaging", July 1997, from now on referred to as Kanai_1997).

Burke discloses an ultrasonic diagnostic system and method for measuring differential backscatter across a selected volume of tissue or organ and detecting temporal and frequency dependencies of backscatter in order to distinguish between normal and diseased tissue (column 1, lines 51-55). Their system includes the steps of transmitting ultrasonic pulses to a living tissue (such as the heart wall), as well as receiving and analyzing the reflected wave of the ultrasonic pulses (column 3, lines 4-25; column 2, lines 3-7). Further, their system includes a processing unit (15) (i.e. analytical processing means) for measuring a backscattering intensity by using a scattering wave from a region of interest in the heart wall on a basis of the received plurality of wave signals, and to detect a variation frequency of the measured backscattering intensity to obtain the diagnostic data to be available (column 2, lines 48-68 through column 3, lines 1-12). See Figure 1. Burke further discloses that their

system includes a means for displaying an image, creating an image based on the diagnostic data, and displaying the image on the display means (column 2, lines 52-53, lines 62-64). However, they do not specifically disclose that their apparatus includes beam scanning means for transmitting an ultrasonic beam having a plurality of ultrasonic pulses to a living tissue while successively changing over the radiating position of said ultrasonic beams, said plurality of ultrasonic pulses being transmitted at a repeated transmission frequency of a few kHz, nor do they disclose that the variation frequency detected is a frequency of tens to hundreds of Hz.

Papadofrangakis et al. disclose a method and ultrasound apparatus for measuring the velocity of blood flow (column 1, lines 6-9). Their system includes the use of a transducer element that is excited to generate pulses of ultrasound with a given emission frequency that insonifies the target (column 1, lines 56-64). As can be seen from Figure 3, their system includes a beam scanning means (11) for transmitting an ultrasonic beam (14) having a plurality of ultrasonic pulses (13) while successively changing over the radiating position of said ultrasonic beams (column 3, lines 25-46). The plurality of ultrasonic pulses is transmitted at a repeated transmission frequency of a few kHz (column 6, lines 8-23). Further, their system includes a reflected wave receiving means (transducer elements/receiving channel) for receiving a plurality of wave signals (column 3, lines 46-60). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include the limitations discussed above to the system of Burke et al. The motivation for doing so would have been to achieve the desired velocity resolution, as taught by Papadofrangakis (column 6, lines 12-15).

However, Burke et al. in view of Papadofrangakis et al. do not specifically disclose that the variation frequency detected is a frequency of tens to hundreds of Hz. Kanai_1997 disclose a method for tracking the movement of the heart based on the acoustic characteristics of the heart muscle (abstract). Their method involves transmitting ultrasonic pulses from an ultrasonic transducer on the chest surface, and then performing calculations on the ultrasonic pulse reflected from the object (pg. 753-755, Section II). Further, they disclose that the measurable frequency band is from d.c. to several hundred Hz (pg. 765, 2nd column, 2nd paragraph). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have the variation frequency of the backscattering intensity be of a frequency of tens to hundreds of Hz. The motivation for doing so would have been that in previous studies involving ultrasonic waves transmitted to the heart, the measurable frequency has been within these limits, as taught by Kanai_1997 (pg. 765, 2nd column, 2nd paragraph).

4. Claims 3-4, 7-9, 12-13, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burke in view of Papadofrangakis et al. and Kanai_1997, and further in view of Kanai et al. ("Real-time Measurements of Local Myocardium Motion and Arterial Wall Thickening", September 1999).

Regarding claims 3-4 and 12-13, as discussed above, the combined references of Burke, Papadofrangakis et al. and Kanai_1997 meet the limitations of claim 1 and 10. Burke's system includes a processing unit (15) that has means for calculating the backscatter intensity from signals provided from a signal processor (13) (column 2, lines 48-62). See Figure 1. Further, Burke discloses that their system detects the variation

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frequency of the backscattering intensity (column 2, lines 61-68 through column 3, lines 1-3). However, they do not specifically disclose that the analytical processing unit further comprises means for calculating a displacement waveform of the region of interest by applying a phased tracking method to the received plurality of wave signals, nor that the backscattering intensity is calculated from the displacement waveform. Kanai et al. disclose the phased tracking method for tracking the movement of the heart wall and arterial wall (abstract). Further, they disclose that the phased tracking method is applied to the reflected ultrasonic pulse and is used to calculate the phase change, average velocity, and displacements (pg. 1231, 2nd column, 4th paragraph – pg.1232). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to have modified the system of Burke to have the processing unit calculate a displacement waveform by applying a phased tracking method to the reflected wave signal. The motivation for doing so would have been to accurately detect small velocity signals, as taught by Kanai et al. (pg. 1230, column 2, 2nd paragraph).

Regarding claims 7-9 and 16-18, Burke discloses that their system includes means for displaying the backscatter intensity or any other backscatter feature for presentation on a display (17) in any desired format (column 2, lines 61-64). See Figure 1. However, they do not specifically disclose that the instantaneous thickness variation velocity of the region of interest on the basis of the variation frequency of the variation cycle of the detected backscattering intensity is displayed, nor that it has a function for converting the variation frequency or variation cycle of the backscattering intensity into a suitable color or density level according to a predetermined color bar or gray scale

superimposed on an M-mode image. Kanai et al. disclose that the velocity signals and change in thickness can be calculated and displayed (pg. 1236-1237, Section VI). Also see Figure 7. They also disclose that they superimpose their results on the M-mode image using a color code (pg. 1231, 1st column, 1st paragraph, and see Figure 5(a)). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to display the instantaneous thickness variation velocity of the region of interest, as well as to convert the variation velocity or variation cycle into a suitable color, superimposed on an M-mode image. The motivation for doing so would have been to be able to provide means for quantitative analysis, and to evaluate the accuracy and performance of the system, as taught by Kanai et al. (abstract and pg. 1238, 2nd column, 2nd paragraph).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

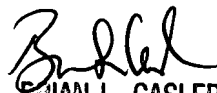
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine L. Fernandez whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni M. Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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